IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1615
	)	
Shalom LEVI et al	)	Examiner: Susan T. Tran
	)	
Appln. No.: 10/086,727	)	Washington, D.C.
	)	
Date Filed: March 4, 2002	)	Confirmation No. 2222
	)	
For: COMPOSITIONS FOR ELIMIN...	)	ATTY.'S DOCKET: LEVI=4

DECLARATION UNDER 37 CFR 1.132

I, Dr. Steve Daren, hereby solemnly declare as follows:

My Curriculum Vitae is attached. I am familiar with the above-identified Levi et al US patent application 10/086,727, including the final rejection mailed April 12, 2005 and the Kobayashi et al US Patent 4,909,986 primarily relied upon by the examiner

Certain tests, set forth below, were carried out by me personally or were carried out under my supervision.

Purpose of Experiments:

The purpose of the following experiments was to test the utility of a polymer solution prepared according to the composition of Kobayashi et al as a film forming, smell reducing agent according to the methodology of the application of Levi et al.

Design of Experiment:

Two sets of experiments were performed. The first was a simulation (see photographs 1 & 2) in which a volatile organic amine (triethylamine) was allowed to permeate through a filter paper which was coated with a polymer film. The time to change the colour of pH indicator solution was determined.

In the second set, pieces of decaying fish which emitted a strong smell were coated with polymer solutions and dried. Again the time to turn a pH indicator from its acid to base colour was determined. (see photographs 3 & 4). This set of experiments corresponded generally to example 23 at column 19 of the Kobayashi patent, as the Kobayashi example coming closest to the Levi et al invention.

Experiment 1: Simulation of Barrier Effect Using Filter Paper.

Materials:

Triethylamine (Fluka, purum >98%)

Phenol Phthalein Indicator , 1% solution in 50:50 ethanol - water solution.

Poly(vinyl alcohol) Moviol 5-88 5% solution in dionized water.

Polyacrylamide (PAM) MW = 10 million - 0.5 and 50 ppm solutions in dionized water.

Polyethylene glycol (PEG 600).

Equipment:

Buchner Funnel - Plastic - 7cm. diameter.

Erlenmeyer Flask - Glass - 125 ml.

Filter Paper GF/F - Whatman -7cm diameter

The head of a disposable white plastic spoon to which was added a drop of the indicator.

An inverted rubber cone of 7cm diameter to hold the filter paper in placeand to support the plastic spoon.

A disposable polystyrene Petrey Dish, 88mm diameter that closed the top of the Buchner Funnel

Disposable Pasteur pipettes

Procedure:

1. The filter papers were weighed. They were then sprayed with the appropriate aqueous polymer solution until the excess solution ran off. The paper was shaken to remove excess drops and then dried overnight in a vacuum oven at 40°C. On removal from the oven, the individual papers were weighed to determine the mass of polymer that had been deposited in the paper.

2. The circumference of the Plastic Buchner Funnel was moistened with PEG 600 fluid as well as the circumference of the dried filter paper. This moist viscous ring ensured that when the paper was placed inside the funnel and the rubber ring was placed on top of it, there would be no leakage of volatiles around the side of the paper. All vapours could exit only via the treated filter paper.

3. The head of the plastic spoon was placed on the rubber cone and 30μl of phenol phthalein solution were added as a single drop in the center of the spoon. At this point the drop was colorless. (The drop size had previously been

calibrated by weighing on an analytical balance. The reproducibilty of the drop size was >95%).

4. The funnel was then closed with the lid of a transparent polystyrene Petrey Dish. This ensured that the volatile gases would accumulate inside the funnel and eventually react with the indicator. The colour of the drop on the white background was easily observed via the Petrey Dish.

5. The complete set up was then placed into the opening of a 125ml Erlenmeyer flask, fitted with a rubber cone and containing 50ml Triethylamine. At this point a stop-watch was started. Vapours of basic triethylamine could now pass through the filter paper into the funnel and react with the phenol phthalein indicator. When sufficient basic vapours had reacted with the indicator and its pH increased to about 8, the drop became pink in color. At this point the stop-watch was stopped.

This experiment was repeated six times for each polymer solution and a blank of untreated filter paper. The better the barrier properties, the longer will be the time needed for the indicator drop to change color.

The polymers tested were polyvinyl alcohol (PVA) in accordance with Levi et al invention, against Polyacrylamide (PAM) according to the Kobayashi et al patent consistent with

Kobayashi, e.g column 6, line 11, as mentioned in the final Office Action at page 4, line 7.

In Table 1, the weights of polymer impregnated into the filter paper are given.

Table 1: Weights of Impregnated Polymer (mg) in GF/F Filter Paper.

Untreated	**PVA 5%**			**PAM 0.5 ppm**			**PAM 50ppm**		
		Net. Increase			Net Increase			Net Increase	
286.1	381.6			289.1			287.4		
290.4	386.2			281.7			289.1		
286.1	383.9			292.0			284.8		
283.1	372.9			285.0			282.8		
282.8	384.2			279.9			288.8		
--	380.8			283.5			282.7		
Average 285.7	**381.6**	**95.9 mg**		**285.2**	**-0.5 mg**		**285.9**	**0.2 mg**	

The weight increase due to the PAM solutions are essentially zero and close to the limits of the sensitivity of the analytical balance (0.1 mg).

In table 2, the times for the indicator to change colour are given. Three papers from each group were tested.

Table 2: Effect of Polymer Barrier on Rate of Diffusion of Triethylamine.

(Minutes:Seconds)

	Untreated	**PVA 5%**	**PAM 0.5 ppm**	**PAM 50ppm**
	6:02	14:25	7:21	6:16
	5:32	17:54	6:39	6:21
	5:44	17:24	6:44	6:00
Average	**5:46**	**16:34**	**6:55**	**6:12**
Effect of Treatment	**---**	**10:48**	**1:09**	**0:26**

The influence of the PAM at concentrations of 0.5 ppm (Kobayashi upper limit) and 50 ppm (much greater than disclosed by Kobayashi) is negligable and hardly exceeds the experimental scatter of the data. The 5% PVA polymer solution (a typical Levi concentration), shows a clear and strong barrier effect that inhibits the passage of the triethylamine through the filter paper.

Experiment 2: Inhibition of Amine Release from Smelly Fish.

Amines are one of the main products of the decomposition of fish and cause much of the associated smell. In this experiment, pieces of smelly fish were coated with polymers and the decrease in the rate of amine release was measured.

Materials:

Aqueous polymer solutions as in experiment 1. We used the PAM at x100 the maximum Kobayashi concentration.

Phenol Red indicator, 0.01% in ethano: water (50:50)

Frozen fish , Barbunia (Red Mullet), 0.5kg. These were kept for four days at room temperature until they started to smell strongly.

Equipment:

Disposable polystyrene Petrey Dishes 88mm diameter.
Automatic liquid dispenser -range 5-50μl (Ependorf)

Procedure:

1. Five individual fish were washed with dionized water. The heads and tails were removed using a scissors and from the central portion of the fish we cut oblong portions approximately 2.5x1.5 cm, weighing 2-3g.

2. Three series of tests were prepared, spray with water only, spray with solution PVA 5% and spray with PAM 50ppm. In each series, three pieces of fish were sprayed until excess water ran off. The fish were then dried in a vacuum chamber at room temperature for 90 mins to generate the polymer film.

3. In parallel with the drying process, nine Petrey Dishes were prepared. Into each dish was placed a white plastic strip onto which three drops of indicator would be places. The rims of each dish and their counter side on the lid were lightly coated with PEG 600 fluid to generate a viscous seal when the lid is closed.

4. The nine dishes, containing their respective pieces of fish, were tested as follows. The fish was placed in the centre of the dish and the plastic strip at the circumference. Three drops of indicator (yellow-acidic) 10μl each, were placed on the plastic strip, and the lid was closed with a slight application of pressure. The stop-watch was started. The time for each of the three indicator drops to turn uniformly pink (basic) was noted. The individual dishes

were tested in a random manner. The actual order is given in table 2 by the subscript a,b,c.....i. The experimental set up is shown in photographs 5 & 6. The results are given in table 2.

Results and Discussion:

The effect of spraying pieces of fish with polymer solutions on the time needed to change the indicator drops from acidic to basic is shown in table 2.

Table 2: Influence of Polymer on Rate of Evolution of Bases from Fish Pieces.

(Time in mins:secs)

Water(Blank)				PAM (50ppm)				PVA (5%)			
No.	Wt g	Time	**Avg.**	No.	Wt g	Time	**Avg.**	No.	Wt g	Time	**Avg.**
1h	2.01	4:20 6:21 5:50	**5:30**	1c	2.25	5:00 8:25 6:30	**6:38**	1a	2.15	11:45 13:10 14:25	**13:07**
2b	2.10	4:15	**5:20**	2f	1.93	6:45	**6:42**	2g	1.98	13:15	**14:45**
		5:30				8:35				14:10	
		6:15				4:45				16:50	
3d	2.10	6:30	**7:13**	3i	3.26	4:15	**4.37**	3e	1.83	13:50	**14:03**
		7:20				5:31				15:20	
		7:50				4:05				13:10	
Avg.	**2.07**		**6:01**		**2.48**		**5:59**		**1.99**		**13:58**
Time Increase			**--**				**0**				**7:57**

The barrier properties of the 5% solution of PVA are clearly demonstrated. On the other hand, a PAM solution similar to that used by Kobayashi et al in examples 23 and 24, but at a concentration one hundred time greater than that used

by Koyabashi et al to bring same closer to the Levi et al invention, show no barrier properties whatsoever.

Conclusions:

The formulations described in Kobayashi et al cannot form the basis for a film forming barrier composition as required in the U.S. patent application of Levi et al. The maximum concentration of the water soluble polymer used in Kobayashi et al (0.5ppm) is 1,000 times or more too dilute to generate the said barrier films.

I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By _____

Dr. Steve Dunn

Date: 11.1.06

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11th Jan. 2006

Curriculum Vitae

STEPHEN L. J. DAREN Ph.D.

Date of Birth	30th October, 1943
Place of Birth	Amersham, England.
Family Status	Married with 3 children
Address	Rehov Hapartizanim,10
	Nes Ziona, Israel, 74037
Telephones	Home: 972-8-9402203
	Laboratory: 972-8-9402942
	Cellular 052 3601963
Fax:	972-8-9409925
Email	steve@darenlab.co.il

Professional Career:

2005	Established Daren Innovation Center
1998	Established Daren Laboratories & Scientific Consultants Ltd.
1990 - 1998	Established Daren Laboratories to provide chemical and technical services.
1982-1998	Private Consultant (see separate list).
1982-1987	Project Leader in Materials Research Dept. Weizmann Institute of Science, Rehovot, Israel. Development of Tribromostyrene Process Research sponsored by "Bromine Compounds Ltd."
1985	Adaptation of the Vofsi-Reich Contact Lens Technology to Soft Hydrogel Contact Lenses.
1984	Assistant to Prof. Ora Kedem Centre for Applied Research , Weizmann Institute of Science, Rehovot, Israel. Responsibilities: Planning new applied research laboratories and setting up temporary scale-up facilities.
1981-1982	Administrative Manager: Indigo R&D Ltd. Kiryat Weizmann, Nes Ziona, Israel. Responsibilities: General Administration of Company including installation of 1,000 m^2 of new laboratories.
1979-1980	Administrative Manager R&D Division, Makhteshim Chemical Works Ltd. Beer Sheva, Israel. Responsibilities: General Administration of R&D Division, government funding and budgeting.
1975-1979	Head of Catalyst Research Laboratory, R&D Division, Makhteshim Chemical Works Ltd. Beer Sheva, Israel. Responsibilities: Process Development including heterogeneous catalysis and Bromostyrene Process.
1967-1975	Weizmann Institute (see Advanced Education)
1967	Immigrated to Israel during Six Days War. Worked as a volunteer in Kibbutz Tel -Yitshak for five months.
1966-1967	Polymer Research Chemist, British Geon Ltd. Barry (Glams.), UK.

Projects: Research into the Thermal and UV. Stabilization of PVC.

Basic Research Experience

Thermal and Ultraviolet Stability of Polymers and Additives.

Synthesis and Characterization of Telomers

Halogenations

Photochemistry

Phase Transfer Catalysis

Molten Salt Catalysis

Gas Phase Pyrolysis

Synthesis and Characterization of Specialty Monomers

Polymerization Kinetics

Optical Properties of Polymers.

Process Development Experience

Dehydrobromination in the Gas Phase

Bromination under pressure in flow reactor

Photohydrobromination of Styrene in batch and flow reactors

Phase transfer elimination reactions in a cascade reactor

Synthesis of Quaternary Ammonium Salts

Halomethylations of Octanol (Warshavsky Process)

Synthesis of Chloromethyl Styrene

Production of Polymeric Reagents (Patchornik Polymers)

Flame Retardant Polymers and their Formulation

Controlled Release Polymers

Hydrogels for Biomedical Applications

Administrative Experience

R&D Management

R&D Project Evaluations

Government Funding

Expert Witness in Patent& Commercial Litigation

Expert Opinions to Helsinki Committee

Expert Opinions to European Union R&D Funding Bodies

Advanced Education

1970-1975	**Ph.D** from the Weizmann Institute of Science, Rehovot, Israel.
	Under the supervision of Profs. David Vofsi and Moshe Levy.
Thesis	Dehydrohalogenation Reactions in the Gas Phase in the Presence of Hydrogen Halide Acceptors: Synthesis of Bromostyrene.
	Sponsored by "Koor Chemicals Ltd." (Israel)
1967-1970	**MSc** from the Weizmann Institute of Science, Rehovot, Israel.
	Under the supervision of Prof.. David Vofsi and Dr. Meir Asscher
Thesis	Cotelomers of Vinyl Chloride as Polymeric Plasticizers for PVC.
	Sponsored by "Pechiney Saint Gobin" Ltd. (France).
1962-1966	**B.Sc.** Honors 2 in Physics and Chemistry from Kings College, University of London, England.

Awards

1974	Shmuel Yaroslavsky Memorial Prize for Applied Research. For work on the Industrial Synthesis of Bromostyrene.
	Awarded by the Scientific Committee of the Weizmann Institute.
1995	Silver Medal: 23rd Salon International des Inventions, Geneva.
	For development of Anti- Smell Formulations for Farms.(with Dr. Shalom Levi.)

Consultancies

Have served as a consultant to the following companies and institutions

3 DP	Adhesives
Advanced Coatings International	Photoresists
Advanced Fine Chemicals	Polymers for Slide Preparations
Altman Technologies	Inorganic Syntheses
America Israel Blades	Lubricating Strip for Razor Blades
Amir Paper Products	Anti- Skin Rash Formulations
Benda Plast	Plastic Packaging
Bromine Compounds	Flame Retardant Monomers and Polymers
Cables of Zion	Analysis of Electrical Insulation Layers
Carbon Membranes	Epoxies
Chemagis	Syntheses and Thermal Analyses
D-Pharm	Thermal Analyses
Electro-Chemical- Research	Ultra-thin Batteries and Fuel Cells
Elan Medical Technologies (Israel) Ltd.	Drug Delivery Systems
ESC Medical Systems	Light Guides
Etrog Biotechnology	Optical Properties of Plastics
European Community	CRAFT Projects Evaluator
Formula Innovations	Anti-smell Formulations
Prof. J. Gale Ben Gurion University	Adhesion
Gat High Tech Center	Project Consultant
Ginegar Plastic Products	Optical Filter for Greenhouses
Halor	Optical Properties of Plastics
Initiative Center of the Negev	Polyurethane Flooring
Israel Defence Forces (Zahal)	
Israel Plastics Institute	Chlorination of Polyethylene
Jaacobson Agencies	Chemical Marketing
Kafrit	Polymer Modification
Kupat Holim Klalit	Purification of Polymer for IVF Use
Makhteshim Chemical Works	Ecology
Matmag	Polyurethane Foams

Minrav (Ambin)	PVC Panels
Prof. D .Mirlmann Weizmann Institute	Scale-up of Allyl Cysteine
Medops Scientific	Intraurethal Device
Meteor Klayman	Evaluation of Failed Polypropylene Nets
Naan Irrigation Systems	Irrigation Tubing
Netzah	PVA Adhesives
Neuro Survival Technologies	Synthesis of Bioactive Polymers
Orlite Engineering	Composite Polymers and Ceramics
Omikron Scientific	Polymer Analysis and Identification
Phoneor	Polymers for Electronic Device
Pliant	Materials for Medical Device
PCJ	Polymeric Reagents
Polyrit	Polyurethane Foams
Proteologics	Polymers for Bioanalyses
Rav Bariach	Insulation of Electronic Device
Power Paper	Membranes for Batteries
Prof. J. Rishpon Tel Aviv University	Custom Syntheses
Romikol	Adhesives Substitution
Prof. I. Rubinstein Weizmann Institute	Organic Synthesis
Salvoplast	Adhesives for Surgical Dressings
Shiran Investments Ltd.	Project Evaluation
Sight line	Materials for Medical Devices
Slilock Ltd.	Adhesive Substitution
Silver Arrow Ltd.	Thermal Analyses
Sigma	Custom Synthesis
Solar Dynamics	Water Treatment Chemicals
Prof. A. Shantzer Weizmann Institute	Polymer Attached Ligands
Serafon	Polymer Analysis
Soflex	Soft Contact Lenses
Sorco Recycling Industries	Plastics Recycling
	Anti Smell Formulations
Tambour	Synthesis of Novel Acrylic Monomers

Taro Research Institute	Polymorphism in Pharmaceuticals
Thelan	Non Mercury Thermometers
Tosaf	Synthesis of Flame Retardants
Trans Scan	Polyacrylamide Membranes
Travinol-Migada	Adhesives for Medical Equipment
Prof. D. Wagner Weizmann. Institute.	Crack Healing in Polymers
Prof. A.Warshawsky Weizmann Institute.	Process Development
X-Analogy	Electrochromic Plastics

Publications and Patents

Telomeric Plasticizers: Cotelomers Based on Vinyl Chloride and Carbon Tetrachloride.
H. Rosin, S. Daren, M. Asscher & D. Vofsi J. Applied Polymer Science16,1687 (1972)

Pyrolysis Study of Bromo- and Chloroethyl Benzenes in Micropulse and Flow Reactors
S. Daren, M. Levy and D. Vofsi Br. Polymer Journal 7, 247 (1975)

Flame Retarded Polypropylene with Good Dyeability (with M. Muskatel et al.)
J. Applied Polymer Science.64: 601-606, (1997).

Homomicronization- A Route for Polymer Recycling. The Newplast Process.
S. Daren. Polimery, 1998,**43**, 6, 379.

US Patent 3,966,831	Production of Bromostyrene
UK Patent 1,378,033	Dibromostyrene
US Patent 1,398,680	Production of Bromostyrene, Dibromostyrene and Alkyl Bromides
US Patent 4,292,453	Process for Preparing Ring Halogenated Styrenes
UK Patent 4,748,286	Production of Crystalline Tribromostyrene
UK Patent 2,164,051	Halogen Containing Telomers
UK Patent 2,193,960	Stabilization of Bromostyrene Monomers
Israel Patent 100540	Flame Retarded Polymethylmethacrylate
US Patent 4,967,02	Process for Production of (Halomethyl)phenethyl bromide
PCT/IL98/00016	Anti Smell Compositions
Israel Application 101684	Novel Terpolymers
US Patent 5,643,68	Non-Liquid Proton Conductors for Use in
EP 0 827 228 B1	Electrochemical Systems in Ambient Conditions.
Israel Application 148578	Flame Retardant Grafted Rubber

Technical Reports:

1974 - 1980	8 Classified Internal Reports for Makhteshim Chemical Works Ltd.
1985	Weizmann Institute to Bromine Compounds Ltd.: Stabilization of Bromostyrene Monomer.
1986	Weizmann Institute to Bromine Compounds Ltd.: Bromostyrene Bench-Scale Pilot..
1987	Weizmann Institute to Bromine Compounds Ltd.: Tribromostyrene Final Report.
1990 - 1999	18 Classified Internal Reports to Bromine Compounds Ltd.

Grants:

Feb. 1978: Prepared and presented the first successful application to the Israel -US .. Binational Industrial Research & Development Foundation - on behalf of Mahkteshim Chemical Works Ltd. **Grant $1,089,000**

Nov. 2,000: European Craft Consortium EN A1 FP5COR: Reduction of Agricultural and Rural Pollution by Innovative Additives **GrantECU 800,000**

Students Supervised for Practical Engineering and Open University Final Projects:

1975	Shabtai Shvili	Pyrolysis of β bromoethylbromobenzene
1977	Eli Shalmashvili	Photohydrobromination of Styrene
1978	Daniella Ganapol	Catalysts for Phase Transfer Reactions
1979	Eli Brender	Effect of Impurities on the Stability of Bromostyrene
1993	Aliza ben Joseph	Polymerization of Bromonitrostyrenes
1993	Eitan Aviv	Acrylate Copolymers of Bromonitrostyrenes
1995	Miah Shalom	Synthesis of Sulfur Containing Acrylates
1996	Tomer Shalom	DSC Evaluation of Emulsion Stability
1999	Yuval Sinai	Synthesis of p-Benzyloxybromobenzene

Participation in Conference Organization.

Organizing Secretary for the **IUPAC** International Symposium on "Polymers for Advanced Technologies", Jerusalem, 1987.

Member of Organizing Committee of Annual Meeting of Israel Chemical Society, Rehovot, Feb. 1989.

Chairman Annual Meeting of Israel Polymer and Plastics Society, Herzlia, Dec. 1992.

Member of Organizing Committee of 23rd. Aharon Katzir Conference on "The Environmental Impact of Polymeric Materials" in framework of Mediterranean Network on Science and Technology of Advanced Polymer - Based Materials. Rehovot, May 1996.

Treasurer of 8th International Conference on Polymer Based Technology (POC'98), Ma;ale Hachamisha, Israel, July, 1998

Membership of Professional Organizations

The American Chemical Society.

The Israel Chemical Society

The Mediterranean Network on Science and Technology of Advanced Polymer - Based Materials.

Israel Polymer and Plastics Society (Treasurer 1992 -1996)